

REMARKS

Claims 23, 24, 26, 27 and 28 are pending in the present application. Claim 23, 24 and 26, 27 and 28 were previously presented and the amendments were not entered. Support for the amendments can be found in the Specification on page 13, lines 3-4; Fig. 25; page 17, lines 19-25; and page 35, line 30. Claim 25 has been canceled without prejudice and without acquiescence. The Examiner has indicated in the Advisory Action dated November 14, 2003 that claim 23 contains allowable subject matter. Further, the Examiner indicated during the Telephonic Interview of January 7, 2004 that the amendments to claims 24 and 26 would put the claims in condition for allowance. Applicants retain the right to file a continuation and/or a divisional application to any canceled claims. No new matter has been added.

The issues outstanding in this application in the Office Action dated August 26, 2003 are as follows:

- Claim 23 was rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Burglin et al. (Genes Dev., 1987).
- Claims 24 and 26 were rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Fu et al. (US Pat No. 6090620, filing date December 1996).

Applicants respectfully traverse the outstanding rejections, and Applicants respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

I. Rejection under 35 U.S.C. § 102(b)

Claim 23 is rejected under 35 U.S.C. § 102(b) as being anticipated by Burglin et al. (Genes Dev., 1987). Applicants respectfully traverse.

Anticipation of a claim is only established where “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

In the previous response dated October 23, 2003, in which the amendment was not entered, Applicants amended claim 23 without acquiescence and prejudice to indicate an isolated polynucleotide having the polynucleotide sequence set forth in Fig. 25 (SEQ ID NO:16). Burglin et al. does not teach the polynucleotide sequence set forth in Fig. 25 (SEQ ID NO:16).

In the Advisory Action, the Examiner indicated that this rejection has been overcome and claim 23 is allowable. Thus, Applicants respectfully request that the amendment be entered.

II. Rejection under 35 U.S.C. § 102(e)

Claims 24 and 26 are rejected under 35 U.S.C. § 102(e) as being anticipated by Fu et al. (US Pat No. 6090620). Applicants respectfully traverse.

Anticipation of a claim is only established where “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

In order to further the prosecution of the present application, Applicants have amended claim 24 without acquiescence and without prejudice to indicate an isolated polynucleotide that specifically hybridizes under hybridization conditions of about 0.3 M NaCl at temperatures of about 50°C to about 55°C with the polynucleotide of claim 23 in which the encoded protein modulates fertility. One of ordinary skill in the art recognizes that the polynucleotide sequence of Fu et al. will not hybridize under the conditions of claim 23

nor does the polynucleotide sequence of Fu et al. encode a protein that modulates fertility. Therefore, Fu et al. is precluded from anticipating the present claim 24. Thus, Applicants respectfully request withdrawal of the rejection.

In order to further the prosecution of the present application, Applicants have amended claim 26 without acquiescence and prejudice to indicate an isolated polynucleotide that is fully complementary to the polynucleotide sequences of claims 23 or 24. In the Advisory Action, the Examiner indicated that previously presented claim 23 was allowable and during the Telephonic Interview the Examiner indicated that amended claim 24 should be allowable. Thus, since dependent claim 26 further includes the limitations of claims 23 and 24, Fu et al. is precluded from anticipating the present claim 26. Thus, Applicants respectfully request withdrawal of the rejection.

III. Response to Advisory action dated February 9, 2004

The Examiner indicates claims 24, 27 and 28 allegedly raise issues under 35 U.S.C. 112, first paragraph. The Examiner indicates that the specification does not describe a sequence wherein the encoded protein modulates fertility and/or ovarian development or function. Applicants respectfully traverse

Well-known case law supports Applicant's position. *Emory University v. Glaxo Wellcome, Inc.*, 44 USPQ 2d 1407 states that "to meet the requirement of §112, the patent application need not utilize any particular form of disclosure. Instead 'the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed'". *In re Alton*, 76 F.3d 1168, 1172 states that "The adequate written description requirement, ...serves 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material'".

Applicants assert that the claims are described and enabled such that one of skill in the art would be able to determine which hybridizable nucleic acid sequences are claimed. Pages 35-36 discuss utilizing an "O1-236 fragment" to measure Npm2 RNA levels. Thus fragment was used under the conditions as claimed to hybridize to Npm2 molecules.

Applicants believe that the Examiner may not have established the link that the term “O1-236” is interchangeable with “NPM2”. For example, claim 24 depends from claim 23, which is the polynucleotide sequence of SEQ.ID.NO. 16, or FIG. 25. FIG. 25 clearly indicates that the sequence is the human NPM2 sequence. In the original claims as filed, one of skill in the art would infer that O1-236 is NPM2, because the claims state “O1-236 (NPM2)”. Still further on page 13, lines 3-4, the Specification states “nucleotide and amino acid sequence O1-236 (SEQ ID NO 16)”. Thus, one of skill in the art would infer that O1-236 is NMP2.

Yet further the Examiner indicates that the specification does not disclose or describe an isolated sequence that hybridizes to the polynucleotide sequence of claim 23. Applicants traverse. The Specification clearly indicates that an “O1-236 fragment” can be used to identify sequences that hybridize to O1-236 and have the indicated function (See Example 8, pages 34-37). The “O1-236 fragment” was used under specific hybridization conditions (which are included in claims 24 and 27) in Northern blot analysis and *in situ* hybridization to determine mRNA expression of Npm2. Example 9 (pages 37-39) of the Specification teach using the “O1-236 fragment” to screen cDNA libraries to identify Npm2 sequences. Thus, Applicants assert that the Specification teaches polynucleotides sequences that hybridize to the polynucleotide sequence of claim 23.

The Examiner further indicates that the Specification does not disclose or describe a sequence wherein the encoded protein modulates fertility and/or ovarian development or function. Applicants traverse. In the specification on page 41, Examples 12 and 13, Applicants provide evidence that NPM2 modulates fertility and/or ovarian development or function. (See Examples 10-14, pages 39-42). Specifically, Example 12 and Table 5 shows that deficiency of Npm2 resulted in subfertility and infertility in females, but not males.

In view of the above arguments, Applicants assert that one of skill in the art would be fully aware that the terms “O1-236” and “NPM2” are interchangeable and that the Specification clearly demonstrates that NPM2 modulates fertility and/or ovarian development or function.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

In an accompanying paper, Applicants have enclosed a request for an extension of time. If any additional fees are required, please charge our Deposit Account No. 06-2375, under Order No. 09807797 from which the undersigned is authorized to draw.

Dated: February 25, 2004

Respectfully submitted,

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